10 November 2011
EMA/CVMP/848821/2011
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure no: EU/ART27/11/193/IMB

Name of the substance: Triclabendazole (INN)

Basis for the opinion

Pursuant to Article 27 of Regulation (EC) No 470/2009 of 6 May 2009, Ireland submitted to the European Medicines Agency on 19 August 2011 a request for an opinion on extrapolation of maximum residue limits for closantel to bovine and ovine milk.

Recommendation

The Committee, having considered the request, recommends by consensus the extrapolation of the maximum residue limits for triclabendazole to milk and the amendment of the entry for triclabendazole in table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

Pharmaco-logically active substance	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Triclabendazole	Sum of the extractable residues that may be oxidised to ketotriclaben dazole	All ruminants	225 µg/kg 100 µg/kg 250 µg/kg 150 µg/kg	Muscle Fat Liver Kidney		Antiparasitic agents/Agents against endoparasites
			10 µg/kg	Milk	Provisional MRL expire on 1 January 2014	

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

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The preliminary analytical method for monitoring of residues is appended to this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 10 November 2011

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)